JUN 2 7 2000

PREMARKET NOTIFICATION SUMMARY

Submitted by: Scandinavian IVF Sciences AB
Mölndalsvägen 30
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SWEDEN

Contact Person: Mr. Eiler Anderson
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Date Prepared: April 16, 1999

Trade Name: G2.2™

Common Name: Assisted Reproduction Media

Classification Name: Reproductive Media and Supplements
(21 C.F.R. § 884.6180)

Predicate Device: Substantial equivalence established by comparison to category of Reproductive Media (21 C.F.R. § 884.6180) as provided in the FDA's Notice of Final Rule, 63 Fed. Reg. 48428).

Description of the Device:

G2.2™ is a bicarbonate-buffered culture media composed of a mixture of balanced salts and other nutrient substances. G2.2™ includes Penicillin-G as a preservative. The media is designed for use for blastocyst culture and embryo transfer during assisted reproduction procedures. G2.2™ is not for use in fertilization.

Intended Use:

For culture of embryos. To be used in culture from 6- to 8-cell stage on day 3 to blastocyst stage on day 5. G2.2™ shall be used after G1.2™.

Technological Characteristics:

The technological characteristics of G2.2™ are identical to other legally marketed culture media classified under 21 C.F.R. § 884.6180, Reproductive Media and Supplements.

Testing Performed:

Because G2.2™ is intended to come into contact with gametes, embryos, and the patient during assisted reproduction procedures, Scandinavian IVF Sciences has conducted biocompatibility testing on the media. This testing included in vitro cytotoxicity and rabbit vaginal irritation assays.

Prior to and as a condition for market release, each lot of G2.2™ is assayed by one-cell Mouse Embryo Assay (MEA) and Limulus Amebocyte Lysate (LAL) Assay. These assays are intended to assure that the media is suitable for its intended use and does not contain unacceptable levels of toxins. Information on these assays is provided on the label and in labeling of the products, and on a LOT-specific Certificate of Analysis provided with each delivery.

The pH and osmolality of each LOT of G2.2™ are also tested prior to release. These tests are conducted according to guidelines issued by the United States Pharmacopoeia and the European Pharmacopoeia. Information on these tests is provided on the LOT-specific Certificate of Analysis provided with each delivery.

G2.2™ has been used for IVF and micromanipulation procedures for many years at many different assisted reproduction facilities. Clinical experience during that time has established its safety and effectiveness for such use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2000

Vitrolife AB/Scandinavian IVF Sciences AB
c/o Mr. Gary L. Yingling
McKenna & Cuneo, L.L.P.
1900 K Street, N.W.
Washington, D.C. 20006

Re: K000619
G2.2™ Assisted Reproduction Media
Dated: May 18, 2000
Received: May 19, 2000
Regulatory Class: II
21 CFR §884.6180/Procode: 85 MQL

Dear Mr. Yingling:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

INDICATIONS FOR USE STATEMENT

510(k) Number: K000619

Device Name: G2.2™
Assisted Reproduction Media

Indications For Use: For culture of embryos. To be used in culture from 6- to 8-cell stage on day 3 to blastocyst stage on day 5. G2.2™ shall be used after G1.2™.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000619

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANTHER PAGE IF NEEDED.)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 C.F.R. § 801.109)